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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/528,326 | 03/07/2006 | Zhengbin Yao | TNX1001 | 7572 |

7590 04/23/2007

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| EXAMINER | |
|---|---|
| HILL, KEVIN KAI | |
| **ART UNIT** | **PAPER NUMBER** |
| 1633 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 31 DAYS | 04/23/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/528,326 | YAO ET AL. | |
| | Examiner | Art Unit | |
| | Kevin K. Hill, Ph.D. | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *31-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-52* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 31-33, drawn to a purified polypeptide comprising an amino acid sequence of SEQ ID NO:2, or a functional variant or fragment thereof.

Group II, Claims 34-37, drawn to an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO:1, or a functional variant or fragment thereof, an expression vector comprising said isolated polynucleotide and an isolated host cell comprising said vector.

Group III, Claims 38-40, drawn to an isolated antibody that binds specifically to the amino acid sequence of SEQ ID NO:2, and a method for producing said antibody.

Group IV, Claims 41-42, drawn to a screening method for identifying NFAT activating receptor agonists or antagonists.

Group V, Claim 43, drawn to a screening method for determining whether an agent is likely to cause undesirable side effects associated with reducing or increasing cytokine and cellular receptor production when administered to an animal for the desired indication.

Group VI, Claims 44-46, drawn to a method for blocking or modulating the expression of a NFAT activating receptor by interfering with the transcription or translation of a DNA or RNA polynucleotide encoding the NFAT activating receptor.

Group VII, Claims 47-48, drawn to a method of diagnosing the predisposition of a patient to develop diseases cause by the unregulated expression of cytokines.

Group VIII, Claim 49, drawn to a method for preventing or treating an NFAT protein mediated disease in a mammal.

Group IX, Claim 50, drawn to a diagnostic method for detecting NFAT activating receptor expressed in specific cells or tissue

Group X, Claim 51, drawn to a method for isolating and purifying NFAT activating receptor from recombinant cell culture, contaminants, and native environments.

Group XI, Claim 52, drawn to a transgenic knockout animal whose genome comprises a heterozygous or homozygous disruption in its endogenous NFAT activating receptor gene that suppresses or prevents the expression of SEQ ID NO:2

2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c). "

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application:

In the instant case, Groups I-III and XI are drawn to distinctly different products that perform distinctly different functions, and are independent and mutually exclusive from each other. The special technical feature of Group I, not present in Groups II-III and XI is an amino acid sequence that is SEQ ID NO:2. The special technical feature of Group II, not present in Groups III and XI is a polynucleotide of SEQ ID NO:1. The special technical feature of Group III, not present in Group XI is an antibody that binds specifically to the amino acid sequence of SEQ ID NO:2. Thus, each of the products possesses a distinctly different structure and biological activity that is independent and mutually exclusive of the other products.

Groups IV-X are drawn to different methods such that each method requires distinctly different process steps, requires the use of distinctly different reagents, has different objectives and do not share a special technical feature. The special technical feature of Group IV, not present in Groups V-X, are method steps to ascertain NFAT receptor activity. The special technical feature of Group V, not present in Groups VI-X, are method steps to ascertain the degree of undesirable side effects associated with cytokine administration. The special technical feature of Group VI, not present in Groups VII-X, are method steps to measure transcription or translation of nucleic acid encoding the NFAT receptor. The special technical feature of Group VII, not present in Groups VIII-X, are method steps of measuring NFAT protein levels from a patient and diagnosing disease predisposition. The special technical feature of Group VIII, not present in Groups IX-X, are method steps to treat disease. The special technical feature of Group IX, not present in Group X, are method steps of detecting NFAT protein in tissue samples using an antibody. Thus, each of the different methods require different process steps, require the use of distinctly different reagents that do not have a shared special technical feature and have different objectives.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CCFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Q. JANICE LI, M.D.
PRIMARY EXAMINER